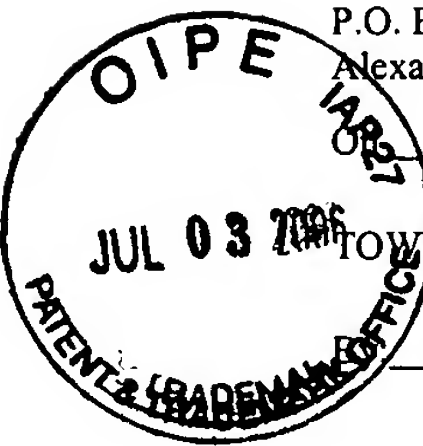


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JUNE 28, 2006

TOWNSEND and TOWNSEND and CREW LLP

*Kimberly Rava*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Gorfine, Stephen R.

Application No.: 10/669,099

Filed: September 22, 2003

For: NITRIC OXIDE DONOR  
COMPOSITION AND METHOD FOR  
TREATMENT OF ANAL DISORDERS

Confirmation No.: 1846

Examiner: Tate, Christopher Robin

Art Unit: 1655

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER  
37 CFR §1.97 and §1.98

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Sir:


The references cited on the attached form PTO/SB/08B are being called to the attention of the Examiner. Copies of the references [in compliance with the requirements of 37 CFR §1.98(a)(2)] are enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

  
Frank J. Mycroft  
Reg. No. 46,946

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Substitute for form 1449A&amp;B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

4

**Complete if Known**

Application Number

10/669,099

Filing Date

September 22, 2003

First Named Inventor

Gorfine, Stephen R.

Art Unit

1655

Examiner Name

Tate, Christopher Robin

Attorney Docket Number

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	ADAMS, M., Declaration of Dr. Michael Adams, including <i>Curriculum Vitae</i> , 22 pages, March 13, 2006.	<input type="checkbox"/>
	2.	AZARNOFF, D.L., Declaration of Daniel L. Azarnoff, M.D., including <i>Curriculum Vitae</i> , 27 pages, October 3, 2003.	<input type="checkbox"/>
	3.	BENET, L.Z. et al., "Section I: General Principles, Chapter 1: Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, and Elimination" in <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 8th Ed., Pergamon Press, pp.1-32 (1980)	<input type="checkbox"/>
	4.	BOUGHTON-SMITH, N.K., "Nitric Oxide Synthase Activity in Ulcerative Colitis and Crohn's Disease," <i>The Lancet</i> , 342:338-340 (1999)	<input type="checkbox"/>
	5.	CELLEGY PHARMACEUTICALS INC., "Corporate Alliances," 2 pages, undated.	<input type="checkbox"/>
	6.	CHAUDHURI, G. et al., "NO is More Important than PGI <sub>2</sub> in Maintaining Low Vascular Tone in Feto-placental Vessels," <i>Am. J. Physiol.</i> 265 (Heart Circ. Physiol. 34):H2036-43 (1993)	<input type="checkbox"/>
	7.	CONANT, C.C., "Plasma Nitroglycerin Levels, Blood Pressure and Apical Heart Rate Variations to Site of Application of Nitroglycerin Ointment," <i>Nurse Practitioner</i> 13(10):56-64 (1988)	<input type="checkbox"/>
	8.	DOLLERY, C.T., Declaration of Colin T. Dollery, MB, Ch.B. FRCP., including <i>Curriculum Vitae</i> , 63 pages, May 24, 2004.	<input type="checkbox"/>
	9.	ERBA, M. et al., "Nitropaste for Prevention and Relief of Vascular Spasm," <i>AJNR</i> , 10:155-56 (1989)	<input type="checkbox"/>
	10.	FLYNN, G.L., Declaration of Gordon L. Flynn, Ph.D., including <i>Curriculum Vitae</i> , 29 pages, May 21, 2004.	<input type="checkbox"/>
	11.	FLYNN, G.L., "Topical Drug Absorption and Topical Pharmaceutical Systems," <i>Modern Pharmaceutics</i> , 2d Ed., pp. 263-64, 89 (1990)	<input type="checkbox"/>
	12.	GIBBONS, R.D., Declaration of Robert D. Gibbons, including <i>Curriculum Vitae</i> , 19 pages, May 13, 2002.	<input type="checkbox"/>

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				Examiner Name	Tate, Christopher Robin
Sheet	2	of	4	Attorney Docket Number	010692-004532US

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	13.	HADGRAFT, J., "Recent Developments in Topical and Transdermal Delivery," Eur. J. Drug Metab. Pharmacokinetics 21(2):165-73 (1996)	<input type="checkbox"/>
	14.	KING, D., Declaration of Denis King, 1 page, December 23, 2000	<input type="checkbox"/>
	15.	KING, D.W., "GTN in the Management of Anal Fissure," presentation slides and cover letter, 9 pages, March 7, 2001	<input type="checkbox"/>
	16.	L'HOPITAL, F. et al., "Constipation et Hypertonie du Sphincter Interne de L'Anus: Response Sphincterienne A L'Administration Sub-Linguale de 0,40 Mg de Natispray," Gastroenterol Clin Biol 14:268 (1990) <i>with English Translation</i>	<input checked="" type="checkbox"/>
	17.	LIPTON, S.A. et al., "A Redox-based Mechanism for the Neuroprotective and Neurodestructive Effects of Nitric Oxide and Related Nitroso-compounds," Nature 364:626-32 (1993)	<input type="checkbox"/>
	18.	LOPEZ-BELMONTE, J. et al., "The Actions of Nitric Oxide Donors in the Prevention or Induction of Injury to the Rat Gastric Mucosa," Br. J. Pharmacol. 108:73-78 (1993)	<input type="checkbox"/>
	19.	LUND, J.N., Declaration of Mr. Jonathan Lund, including <i>Curriculum Vitae</i> , 29 pages, March 6, 2003.	<input type="checkbox"/>
	20.	MAHAJAN, R.P. et al., "Topical Nitroglycerin Prevents the Pressor Response to Tracheal Intubation and Sternotomy in Patients Undergoing Coronary Artery Bypass Graft Surgery," Anaesthesia 48:297-300 (1993)	<input type="checkbox"/>
	21.	MATHEIS, G. et al., "Role of L-arginine-nitric Oxide Pathway in Myocardial Reoxygenation Injury," Am. J. Physiol. 262:H616-20 (1992)	<input type="checkbox"/>
	22.	MEDICAL ECONOMICS, PHYSICIANS, <u>Physicians' Desk Reference</u> , 46 Edition, pp.1004-1006; 1164-1166 (1992).	<input type="checkbox"/>
	23.	MERCK & CO., INC., "The Merck Manual of Diagnosis and Therapy, Section 3: Gastrointestinal Disorders, Chapter 35: Anorectal Disorders, General" retrieved online at < <a href="http://www.merck.com/mrkshared/mmanual/section3/chapter35/35a.jsp">http://www.merck.com/mrkshared/mmanual/section3/chapter35/35a.jsp</a> > on February 14, 2005.	<input type="checkbox"/>

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	24.	PARTEQ INNOVATIONS, "Cellegy Pharmaceuticals Acquires PARTEQ Spinoff Vaxis," 2 pages, Nov. 28, 2001	<input type="checkbox"/>	
	25.	PAVLICK, K.P. et al., "Role of Reactive Metabolites of Oxygen and Nitrogen in Inflammatory Bowel Disease," Free Radical Biology & Medicine 33(3):311-322 (2002)	<input type="checkbox"/>	
	26.	PIAZZA, C.T., Declaration of Christin T. Piazza, 2 pages, May 15, 2002	<input type="checkbox"/>	
	27.	RANADE, V.V., "Drug Delivery Systems. 6. Transdermal Drug Delivery," J. Clin. Pharmacol. 31:401-418 (1991)	<input type="checkbox"/>	
	28.	ROMANELLI, M. et al., "The Effect of Topical Nitroglycerin on Transcutaneous Oxygen," British Journal of Dermatology 124:354-357 (1991)	<input type="checkbox"/>	
	29.	SANDRINI, A. et al., "Effect of Montelukast on Exhaled Nitric Oxide and Nonvolatile Markers of Inflammation in Mild Asthma," CHEST 124:1334-1340 (2003)	<input type="checkbox"/>	
	30.	SCHOLEFIELD, J.H. et al., "A Dose Finding Study with 0.1%, 0.2%, and 0.4% Glyceryl Trinitrate Ointment in Patients with Chronic Anal Fissures," Gut 52:264-69 (2003)	<input type="checkbox"/>	
	31.	SCHOLEFIELD, J.H., Declaration of John Howard Scholefield, including <i>Curriculum Vitae</i> , 47 pages, Feb. 28, 2005.	<input type="checkbox"/>	
	32.	SCHOUTEN, W.R., "Pathophysiological Aspects and Clinical Outcome of Intra-Anal Application of Isosorbide Dinitrate in Patients with Chronic Anal Fissure," Gut 39(6):465-469 (1996)	<input type="checkbox"/>	
	33.	SHERMAN, M.P., "Nitric Oxide-Mediated Neuronal Injury in Multiple Sclerosis," Medical Hypotheses 39:143-146 (1992)	<input type="checkbox"/>	
	34.	SHIVELY, M., "Effect of Nitroglycerin Ointment Placement on Headache and Flushing in Healthy Subjects," Int. J. Nurs. Stud., 28(2):153-161 (1991)	<input type="checkbox"/>	
	35.	VAN REEMPTS, P. et al., "Topical Use of Nitroglycerin Ointment in Neonates," Editorial Correspondence, J. Pediatr, 116(1):155 (1990)	<input type="checkbox"/>	
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	36.	WEINHARDT, J.A., "Making the Most of Topical Nitroglycerin," RN 48(12):38-40 (1985)	<input type="checkbox"/>

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